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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,364

Applicant(s)

VAN POELJE ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 12-114 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 1-10, 12-14 are pending in this application. Claims 1-5, 12-18, and 20-45 are currently under examination on the merits. It is noted that claims 46-114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention; Claims 6-10 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected specie, of record in the Office Action dated February 17, 2004. Claim 11 has been canceled on the Amendment filed on October 26, 2005.

A new Restriction Requirement to claims 1-5, 12-18, and 20-45 is hereby required under 35 U.S.C. 121:

Claims 1-5, 12-18, and 20-45 are generic to a plurality of disclosed patentably distinct species comprising various insulin secretagogue selected from a group of patentably distinct compounds, and FBPase inhibitors selected from a group of patentably distinct compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

It is considered that a Markush-type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a reference anticipating one of the species would not anticipate or render obvious the other species. Further, the species are considered to be independent since they are unrelated in functional structure, properties and operation, because one does not require the other for ultimate use, and specification does not disclose a dependent relationship between them. The instant claims as

Art Unit: 1617

presented contain such a number of possibilities and permutations that it is not possible to identify each and every species encompassed in the claims. Accordingly, a requirement to provisionally elect a single independent and patentably distinct species is made as provided for in MPEP § 803.02 because, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

In the event that the Markush-type claims are not found to be allowable, the examination of the claims presented will be limited to the Markush-type claims to the extent that they read on the elected species and claims directed solely to the elected species. The claims directed solely to the non-elected species will be held withdrawn from consideration. See MPEP § 803.02.

Claims 1, 3-4, 12, 14, 16, 20, 22, 23, 25-43 are drawn in Markush format, encompassing independent and patentably distinct compounds groups. Upon election of a species, the examination of claims commences to the extent that it reads on an articulated subgenus encompassing the elected species.

By species is meant a single compound. The compound may be named in any of following ways (or any combination thereof): (a) by a pictorial representation of the compound, (b) by setting forth the specific chemical group that each variable of the Markush group represents, or (c) by naming a claim or an example which itself sets forth a single compound.

Since the instant claims are drawn to a composition of matter which contains more than one group of compounds, a single compound (as described above) should be elected for each group of compounds. It is not necessary to elect a single compound

for groups of compounds, which are inert and have no bearing on the patentability of the composition (e.g. it would not usually be necessary to elect which solvent or buffer system the composition will be associated with.)

The following species require a clear election:

1. Insulin secretagogue and further whether the elected species is a sulfonylurea or a non-sulfonylurea antidiabetic agent
2. FBPase inhibitor and further whether the elected species is within the subgenus of Formulae I or IA

Subsequent to the selection of a above recited species, Applicant is requested to identify the specific functional groups attributed to each of the elected species. For example, if formula I is elected as the FBPase inhibitor, the following functional group must also be identified: (a) M and its respective functional groups, (b) Y and its respective attachments and their functional group, and (c) R1-R16 if applicable.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mr. Eisenschank on February 16, 2006 to request an oral election to the above restriction requirement, but did not result in an election

Art Unit: 1617

being made. Further, due to complexity of the requirement, no further telephonic follow up was made.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENIVASAN PADMANABHAN
SUPERVISORY PATENT EXAMINER